BASF Corporation

8EHQ-1202-15244

64887

BASF

Certified Mail 7000 0520 0015 4099 3225
Return Receipt Requested

December 10, 2002

Attention: 8(e) Coordinator
U. S. Environmental Protection Agency
Document Control Officer
Office of Pollution Prevention and Toxic Substances, 7407
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Contain NO CBI

Ladies and Gentlemen:

Subject: Notice in Accordance with TSCA Section 8(e) – Results of an OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar Rats

On behalf of the Global Producers of Alkylketendimers (GPA) consortia, BASF Corporation is submitting results of an OECD 422 Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test in Wistar rats (strain Alpk: AP_fSD) with Aquapel 364 (CAS # : 68390-56-7). The IUPAC name for Aquapel 364 is 3-(C_{2-16}alkyl)-4-(C_{13-17}alkylidene)-2-oxetanone. The study was conducted as part of the voluntary High Production Volume (HPV) Challenge Program and the International Council of Chemical Associations (ICCA) Global Initiative. This test was conducted by Central Toxicology Laboratory, Alderley Park Maccelsfield Cheshire, United Kingdom. The GPA consortia is comprised of the following members: BASF Aktiengesellschaft, EKA Chemicals AB, Hercules BV, Kemira Chemicals Oy, NOF Corporation, Raisio Chemicals Oy and MARE S.P.A.

Methods:

The study was carried out in accordance with the requirements of the following international guidelines: OECD Guidelines for Testing of Chemicals, Guideline 422 and EPA, Health Effects Test Guidelines; OPPTS 870.3650. The test substance was administered in corn oil by oral gavage to 10 male and female rats per group at doses of 0, 100, 350 and 1000 mg/kg body weight. The males were treated for approx. 4 weeks. In females, treatment lasted from 2 weeks pre-mating, during mating (2 weeks) and gestation through day 4 of lactation.

Summary of Relevant Results:

- No compound related adverse effects were observed for mortality, clinical changes, body weight, food consumption, neurotoxicity, or macroscopic evaluation for both sexes.
- No compound related adverse effects were observed on pup evaluation parameters (i.e. not teratogenic) and there were no signs of developmental toxicity.

1609 Biddle Avenue, Wyandotte, Michigan 48192 Telephone (734) 324-6000

- A reduced proportion of implantation sites compared to the numbers of corpora lutea in all dose groups (100, 350, 1000 mg/kg), but without a clear dose-response relationship.
- Increase in total white blood cell count (large unstained cells, lymphocytes, monocytes) in both sexes (females: increase in basophils), and all dose groups (100, 350, 1000 mg/kg).
- Increase in total bilirubin, and cholesterol in both sexes and in albumin, total protein and plasma calcium in females at a dose level of 1000 mg/kg and 350 mg/kg. Increase in spleen and liver weight in both sexes and all dose groups. In the females an increase in kidney weights in all dose groups, in ovaries at 1000 mg/kg and 350 mg/kg only.
- Macroscopically, spleen and lymph nodes were enlarged in the females at all dose groups.
- Microscopically, inflammatory changes were seen in a variety of tissues (e.g. liver, lymph nodes, kidneys, cervix, jejunum) in both sexes at all dose groups groups (100, 350, 1000 mg/kg). Severity, distribution, and the overall incidence was greater in females.

Although the findings are not considered to present a substantial risk to human health or the environment, BASF Corporation understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy.

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot

Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations

mk